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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,221

02/28/2006

Ute Linemann

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EXAMINER

PAGE, BRENT T

ART UNIT

PAPER NUMBER

1638

NOTIFICATION DATE

DELIVERY MODE

07/09/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

Office Action Summary	Application No. 10/565,221	Applicant(s) LINEMANN ET AL.	
	Examiner BRENT PAGE	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,8-14 and 18-30 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,8-14 and 19-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 January 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, SEQ ID NO:2 in the reply filed on 04/15/2008 is acknowledged. The traversal is on the ground(s) that the technical feature linking the inventions is a bidirectional promoter rather than promoter sequences. This is not found persuasive because the claims are not limited to bi-directional promoters, do not mention bi-directional promoters, and are sufficiently broad to encompass promoters that are not bi-directional, therefore the technical feature linking the inventions is promoter sequences rather than bi-directional promoter sequences.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 8-14 and 19-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the promoter sequence of SEQ ID NO:2, does not reasonably provide enablement for nucleic acid sequences comprising, fragments of at least 25 consecutive bases having "substantially the same promoter activity" of SEQ ID NO:2, sequences having at least 80% sequence identity to SEQ ID NO:2, or any functional fragments thereof. The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn to expression cassettes comprising fragments of at least 25 consecutive bases having “substantially the same promoter activity” of SEQ ID NO:2, sequences having at least 80% sequence identity to SEQ ID NO:2, or any functional fragments thereof wherein said regulatory element is disposed between two nucleic acid sequences and at least two ribonucleic acids are expressed.

In contrast, the specification only provides guidance for the full length sequence of SEQ ID NO:1 or SEQ ID NO: 2 for use as a promoter sequence. The specification does not provide guidance for any other sequences, or fragments of sequences for use as promoters.

The function of promoter fragments and sequence variants in transgenic plants is unpredictable. Kim et al (1994, Plant Molecular Biology 24:105-117) in a mutational analysis of the nopaline synthase promoter in a stable transformation system, found that mutation of a single nucleotide significantly altered the strength of expression, while deletions in other regions of the promoter completely eliminated function (page 108 first full paragraph).

Deletion analysis of promoters is unpredictable. Donald et al (1990, EMBO J. 9:1717-1726) teach that a crucial promoter element for the *Arabidopsis* rcbS-1A promoter is located in the region about 250 bases upstream of the transcription initiation site.

Furthermore, the function of promoter fragments and sequence variants in transgenic plants is unpredictable wherein the promoter function is regulated by conditional elements. Dolferus et al (1994, Plant Physiology 105:1075-1087) in a deletion analysis of the *Arabidopsis Adh* promoter, found that deletion of different elements of the promoter affected promoter function conditional to the stress that was applied to the given promoter fragment (page 1080, last full paragraph and page 1082 first full paragraph).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate all promoter-effective molecules that would give bi-directional expression in plants as broadly claimed.

Claims 1-4, 8-14 and 19-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to expression cassettes comprising fragments of at least 25 consecutive bases having "substantially the same promoter activity" of SEQ ID NO:2, sequences having at least 80% sequence identity to SEQ ID NO:2, or any functional fragments thereof wherein said regulatory element is disposed between two nucleic acid sequences and at least two ribonucleic acids are expressed.

In contrast, the specification only provides description for the full length sequence of SEQ ID NO:1 or SEQ ID NO: 2 for use as promoter sequences. The specification does not provide description of any other sequences, or fragments of sequences for use as promoters. The specification further does not describe which structural features of SEQ ID NO:2 are critical for function as a promoter.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function

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and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 8-14 and 19-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Budworth et al (WO200198480).

The claims are broadly drawn to expression cassettes comprising fragments of at least 25 consecutive bases having "substantially the same promoter activity" of SEQ ID NO:2, sequences having at least 80% sequence identity to SEQ ID NO:2, or any functional fragments thereof wherein said regulatory element is disposed between two nucleic acid sequences and at least two ribonucleic acids are expressed.

Budworth et al teach a regulatory sequence depicted in SEQ ID NO:315 exhibiting 99.8% sequence identity with SEQ ID NO:2 that would inherently have the same promoter activity of SEQ ID NO:2 (see SEQ ID NO:315). Budworth also teach heterologously linking the promoter sequence to both sense and antisense RNA sequences (see claims 5 and 24-28) in plants and expressing selection markers such as hygromycin and glyphosate and target genes (see claims 31-39 and 78-80 and pages 47, 56-58 and 75-76 where selection genes and target genes are described in great detail). Budworth further teach the insertion of the promoter sequence between two heterologous sequences (see pages 18-19, for example) such as an enhancer and a gene but wherein two gene products are heterologously produced, one target gene and one marker gene and particular two or more genes (see page 80). The regeneration of the plants would inherently produce the seed of claim 29.

No claims are free of the prior art. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Russell Kallis/

Primary Examiner, Art Unit 1638

7/02/2008